K032801

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OCT 17 2003

Special 510(K) Summary
Albert Browne Ltd.
Modified Browne Packaging and Label Steam Process Indicator

1. **SUBMITTED BY:** Albert Browne Ltd.
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

CONTACT PERSON: Alan Charlton
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

DATE PREPARED: September 8, 2003

2. **DEVICE NAME:** Modified Browne Packaging and Label Steam Process Indicator

CLASSIFICATION NAME: Physical/chemical sterilization process indicator

CLASSIFICATION STATUS: Physical/chemical process indicators are classified as Class II under Sterilization process indicator in 21 CFR 880.2800 (Product Code JOJ) by the General Hospital and Personal Use Devices Panel

3. **PREDICATE DEVICE**

Browne Packaging and Label Steam Process Indicator (K992767)

4. INTENDED USE

The Modified Browne Packaging and Label Steam Process Indicator (Modified Packaging and Label Steam Indicator) is a process indicator which undergoes a visual color change when exposed to steam in a temperature range of 121°C to 135°C (250°F to 275°F).

5. DEVICE DESCRIPTION

Like the parent Browne Packaging and Label Steam Indicator, the proposed Modified Packaging and Label Indicator consists of indicator ink applied to a suitable substrate using a flexographic printing method. When exposed to steam in the temperature range of 121°C to 135°C (250°F to 275°F), the indicator changes color. The parent indicator changed color from pink to purple. The color change for the proposed indicator is from pink to dark purple. Neither the proposed or parent indicator is intended to indicate that specific sterilization parameters have been met, but simply that the indicator has been exposed to a steam process.

6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the proposed Modified Packaging and Label Steam Indicator and the parent indicator are identical. The proposed and predicate devices consist of indicator ink applied to a substrate. The indicator ink changes color to confirm exposure to steam.

The Modified Packaging and Label Steam Indicator consists of indicator ink applied using a flexographic printing method to packaging material, self-adhesive labels, tapes, tags, inserts, etc. The indicator ink composition for the proposed Modified Packaging and Label Indicator was modified to make the ink compatible with multiple substrates and improve the intensity of the visual color change.

The substrates used to support the indicator ink are identical for the proposed and predicate devices. The substrates for both the proposed and parent indicators are clay-coated label stock (some containing permanent or peelable adhesive and a siliconized backing) and steam-sterilizable paper.

The composition of the indicator ink used for the proposed Modified Packaging and Label Indicator was modified to make the ink compatible with multiple substrates and increase the intensity of the color change. The chemical reaction that induces the indicator ink to change color is identical for the parent and proposed indicators. The

effective temperature range of the proposed device was expanded to include a 135°C steam sterilization cycle.

7. PERFORMANCE TESTING

Albert Browne Ltd. has performed testing which demonstrates that the Modified Browne Packaging and Label Steam Indicator conform to the applicable requirements of ANSI/AAMI ST60 for Class I process indicators for steam sterilization. Additional testing showed that the indicator performed as designed in 132°C, 134°C, and 135°C sterilization cycles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2003

Albert Browne Limited
C/O Dr. Cynthia J.M. Nolte Ph.D.
Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K032801
Trade/Device Name: Modified Browne Packaging and Label Steam Process Indicator
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: September 8, 2003
Received: September 22, 2003

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

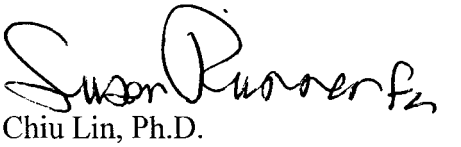
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032801

510(k) Number (if known):

Device Name: Modified Browne Packaging and Label Steam Process Indicator

Indications for Use:

The Modified Browne Packaging and Label Steam Process Indicator is a process indicator which undergoes a visual color change when exposed to steam in a temperature range of 121°C to 135°C (250°F to 275°F).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Pat Alt, Steven Browne Chief, INCB, 10/17/03
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number: K032801

Prescription Use ______ OR Over-The-Counter Use ______

(Per 21 CFR 801.109)